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No. 94-818

IN THE
Supreme Court of the United States
OCTOBER TERM, 1994

HERCULES, INCORPORATED,

and

WM. T. THOMPSON COMPANY
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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BRIEF FOR THE NATIONAL VETERANS LEGAL SERVICES PROGRAM AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Amicus curiae will address only the following question:

Whether credible scientific evidence now exists supporting an association between exposure to dioxin (which was contained in Agent Orange sprayed in Vietnam) and various cancers and other diseases suffered by Vietnam veterans.

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59 Fed. Reg. 5,161 (1994) (proposed rule) (codified at 38 C.F.R. § 3.309 (1994)) 8

OTHER AUTHORITIES

Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides, Institute of Medicine, National Academy of Sciences, *Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam* (1994) 4, 5, 6, 7
Peter H. Schuck, *Agent Orange on Trial: Mass Toxic Disasters in the Courts* (1986) 8

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BRIEF FOR THE NATIONAL VETERANS LEGAL SERVICES PROGRAM AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

This brief *amicus curiae* is filed with the consent of the parties, as provided for in the Rules of this Court.

INTEREST OF *AMICUS CURIAE*

The National Veterans Legal Services Program ("NVLSP") is a non-profit, tax-exempt organization that serves as a national support center in the area of veterans law, including disability compensation cases. The NVLSP regularly represents veterans before the United States Court of Veterans Appeals and in various other federal courts. The NVLSP also publishes informational materials

for veterans and their advocates and conducts training events for veterans advocates. The services of the NVLSP are provided to individual veterans and classes thereof, national veterans service organizations, state and county veterans offices, community-based veterans organizations, volunteer attorneys, private bar attorneys, legal services attorneys, and other veterans advocates nationwide. The NVLSP has assisted and continues to assist Vietnam veterans in obtaining compensation through administrative and judicial means for health problems resulting from exposure to Agent Orange.

INTRODUCTION AND SUMMARY OF ARGUMENT

From 1962 to 1971, millions of gallons of defoliant, including principally "Agent Orange,"[1] were sprayed over Vietnam in support of military operations. Produced in accordance with government specifications, Agent Orange contained dioxin, one of the most toxic substances known to science. Since the war, many American veterans who were exposed to Agent Orange while serving their country have suffered, and continue to suffer, from an array of physical illnesses, diseases, and death.

In its Brief For the United States in Opposition, the government argued that one ground for upholding the Federal Circuit's decision is that there is no credible evidence to support the claim that Agent Orange caused any health problems in veterans exposed to it (Resp't Br. in Opp'n to Cert. 11, 14-15) ("Resp't Br."). Absent evidence supporting causation, the United States asserts, petitioners would not have been liable to the veteran class members had the case gone to trial. *Id.* at 11, 14-

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[1] Agent Orange is a 50/50 blend of 2,4-Dichlorophenoxyacetic Acid (2,4-D) and 2,4,5-Trichlorophenoxyacetic Acid (2,4,5-T). The chemical processes of making 2,4,5-T necessarily create some amount of 2,3,7,8-Tetrachlorodibenzo-*p*-dioxin ("dioxin").

15. Therefore, petitioners' costs of settling the class action were not caused by any alleged dangers of Agent Orange, but rather by petitioners' voluntary decision to settle the class action. *Id.* at 7-8.

The NVLSP objects to the United States' suggestion that there is no credible evidence that Agent Orange caused any health problems to Vietnam veterans. The government ignores substantial, credible scientific and medical evidence that supports an association between dioxin exposure and certain cancers and other serious diseases suffered by many Vietnam veterans. After reviewing a vast amount of this evidence, the National Academy of Sciences (NAS) so found. Even the Secretary of Veterans Affairs, who commissioned the NAS's exhaustive review, has concluded that the credible scientific evidence in favor of an association between exposure to dioxin and certain diseases is equal to or outweighs the credible evidence against such an association.

ARGUMENT

I. CREDIBLE SCIENTIFIC EVIDENCE SUPPORTS FINDING AN ASSOCIATION BETWEEN EXPOSURE TO DIOXIN (WHICH WAS CONTAINED IN AGENT ORANGE SPRAYED IN VIETNAM) AND VARIOUS CANCERS AND OTHER DISEASES SUFFERED BY VIETNAM VETERANS.

The government argued in its Brief For the United States in Opposition that one ground for upholding the Federal Circuit's decision in favor of the government is that there is no credible evidence to support the claim that Agent Orange caused any health problems in veterans exposed to it (Resp't Br. 11, 14-15). The government relies in part on this purported absence of causation evidence to support its argument that petitioners would not have been liable to the veteran class members had the case gone to trial and, therefore, the petitioners' costs of settling the Agent Orange Litigation [2] were not caused by the gov-

ernment but rather by the petitioners' voluntary decision to settle. According to the government, petitioners' chances of facing actual liability in the Agent Orange Litigation were so remote as to "necessarily imply[] that petitioners' settlement could not have been 'reasonable.'" (Resp't Br. 20).

The United States' assertion of an "absence of scientific evidence regarding the consequences of dioxin exposure" (Resp't Br. 11) flies in the face of the now available scientific evidence, the conclusions of the National Academy of Sciences (NAS), and the findings of the Secretary of Veterans Affairs. Credible scientific evidence supports finding that it is more likely than not that dioxin causes various diseases in human beings. Numerous Vietnam veterans suffer from these diseases.

Between 1962 and 1971, the United States military sprayed approximately 11.2 million gallons of Agent Orange over approximately 3.6 million acres in Vietnam. These large-scale spraying operations spread herbicides to defoliate potential ambush areas and to destroy the enemy's crops. From the first reports of the use of the chemicals in 1964, groups of scientists, including the American Association for the Advancement of Science, banded together to oppose the use of the chemicals. See Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides, Institute of Medicine, National Academy of Sciences, *Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam* 29 (1994) ("NAS Report"). In 1969, the first scientific report found that one of the primary chemicals in Agent Orange caused birth defects in laboratory animals. See *id.* at 30 (citing Bionetics Research Laboratories, *Evalu-*

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[2] *Agent Orange Litigation* refers to the class action brought by Vietnam veterans against the United States and various herbicide manufacturers including the petitioners. *See In re "Agent Orange" Prod. Liab. Litig.*, 597 F. Supp. 740 (E.D.N.Y. 1984).

ation of Carcinogenic, Teratogenic and Mutagenic Activities of Selected Pesticides and Industrial Chemicals (1968)). In response, the United States Army suspended use of Agent Orange in 1970 and all herbicide spraying operations in 1971.

After years of struggle within the scientific community and in the Agent Orange Litigation, Congress recognized a need for an objective scientific appraisal of the association between the increased risk of disease and exposure to Agent Orange and the other herbicides used in support of military operations in Vietnam. Accordingly, Congress required the Secretary of Veterans Affairs to agree to a review of the issue by the NAS. See Agent Orange Act of 1991, Pub. L. No. 102-4, § 3, 105 Stat. 11, 13-15 (codified as amended at 38 U.S.C. § 1116 (1991)). The NAS committee was charged with evaluating the strength of the scientific evidence as to an association between human exposure to the herbicides and suspect diseases.

Created by an Act of Congress, the NAS is a non-governmental, non-profit society of distinguished scholars with a mandate to advise the federal government on pressing scientific and technical issues. Its members are elected by their peers from universities and the private sector, and the members serve without compensation. For its Agent Orange committee, the NAS gathered a group of eminent professionals, all of whom had no conflicts of interest, and none of whom had taken public positions on the potential health effects of herbicides. See NAS Report at vii, 764-70.

In preparation for its report, the NAS committee conducted an exhaustive review of the available evidence—reading 6,420 abstracts, performing detailed review and analysis of 230 epidemiological studies, holding three formal public hearings, and consulting with outside experts. See NAS Report at xi-xiii, 735-56. In assessing the relative validity of studies, the NAS critiqued the

methods of its peers and based its conclusion that there was a "positive association" between herbicide exposure and five specific diseases only on studies that eliminated chance, bias, and confounding with reasonable confidence. *Cf. Daubert v. Merrell Dow Pharmaceuticals*, 113 S. Ct. 2786, 2795-99 (1993) (proposing similar criteria). In this process, the committee considered several factors for each possible association including its statistical strength, dose-response relation, temporal relation between exposure and onset, consistency across studies, specificity, and biologic plausibility.[3] See NAS Report at 238-40. While there is much more credible evidence favoring an association between dioxin exposure and illness as to some diseases than to others, the NAS Report demonstrates, at a minimum, the existence of a material issue of fact with respect to a number of diseases.

Based on this extensive review, the NAS committee concluded that "sufficient evidence" exists to find a "positive association" between exposure to Agent Orange and the onset of three cancers: soft tissue sarcoma,[4] non-Hodgkin's lymphoma,[5] and Hodgkin's disease.[6] See *id.* at 6-10, 475-501, 525-64, 572-74. The committee also found "sufficient evidence" of a "positive association" between

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[3] Animal studies demonstrate the plausible biological mechanism of dioxin's actions. These studies establish that dioxin "interacts with an intracellular protein called the Ah receptor [and that] this interaction appears to play a role in a number of health effects observed in animals. Because humans also have intracellular proteins identified as Ah receptors, [the] interactions [of dioxin] and [the Ah] receptors could play a role in human health effects." NAS Report at 3.

[4] A diverse group of malignant neoplasms (tumors) in the areas within and between organs. See *id.* at 782.

[5] A diverse group of malignant lymphomas, that is, tumors derived from cells in the lymph nodes, without the giant Reed-Sternberg cells characteristic of Hodgkin's disease. See *id.* at 781.

[6] A malignant lymphoma characterized by progressive enlargement of the lymph nodes, liver, and spleen, and by progressive anemia. See *id.* at 780.

Agent Orange and two severe skin conditions: chloracne [7] and porphyria cutanea tarda (PCT).[8] See *id.* at 6-10, 672-83. Moreover, the committee found evidence "suggestive" [9] of an association between the herbicides used in Vietnam and respiratory cancers (lung, larynx, and trachea), prostate cancer, and multiple myeloma.[10] See *id.* at 6-10, 460-75, 512-22, 574-76.

The NAS's conclusions following its exhaustive review and analysis of the scientific evidence concerning the toxicity of Agent Orange illustrate the genuine dispute that exists as to the causal relationship between exposure to Agent Orange and veterans' health problems. After the NAS Report, the Department of Veterans Affairs (VA), which had resisted acknowledging the dangers of Agent Orange, reviewed the NAS Report and "all other sound medical and scientific information." 38 U.S.C. § 1116(b)(2) (1991). The VA concluded that the credible evidence in favor of an association between herbicide exposure and disease is at least as strong as the credible evidence against such an association as to all five diseases for which the NAS has found "sufficient evidence," and four of the five diseases for which the NAS has found "suggestive evidence." In making this determination, the Secretary of Veterans Affairs was required to consider

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[7] An acne-like eruption, evident shortly after exposure, which produces persistent comedones, keratin cysts, and inflamed papules causing hyperpigmentation and lesions often resulting in a characteristic scarring pattern. See *id.* at 779.

[8] An uncommon disorder of porphyrin metabolism manifested in thinning and blistering of skin in sun-exposed areas in addition to excess skin pigmentation and excessive hair growth. The committee limited its finding to genetically susceptible persons. See *id.* at 781.

[9] For this latter category of cancers, the committee could not confidently eliminate possible chance, bias, or confounding. See *id.* at 6, 674-75.

[10] Cancer of specific bone marrow cells characterized by tumors in the marrow of various bones; more specifically, a malignant proliferation of plasma cells derived from B lymphocytes. See *id.* at 781.

whether the results were "statistically significant, . . . capable of replication, and [could] withstand peer review." 38 U.S.C. § 1116(b)(2) (1991).

In 1991, the VA concluded that a positive association exists between exposure to Agent Orange and the subsequent development of soft tissue sarcoma and reaffirmed its earlier determination of such an association with chloracne. See 56 Fed. Reg. 51,651 (1991) (sarcoma); 56 Fed. Reg. 52,473 (1991) (chloracne). Although the VA had initially denied an association between herbicide exposure and PCT, after the NAS study, the VA found credible evidence of such a linkage. Compare 56 Fed. Reg. 52,473-74 (1991) (denying association with PCT) with 58 Fed. Reg. 50,528-29 (1993) (finding credible evidence of such an association). Similarly, the VA has found associations with non-Hodgkin's lymphoma and Hodgkin's disease, as well as with respiratory (lung, larynx, and trachea) cancers and multiple myeloma. See 59 Fed. Reg. 5,161-62 (1994) (proposed rule) (codified at 38 C.F.R. § 3.309 (1994)). The NAS Report has thus altered the "one principle firmly embedded in [the VA's] bureaucratic mind" that "any problems suffered by veterans exposed to Agent Orange . . . were not, with the exception of chloracne, caused by the herbicide." Peter H. Schuck, *Agent Orange on Trial: Mass Toxic Disasters in the Courts* 24 (1986).

Moreover, the VA has not merely made formalistic findings of a positive association between dioxin exposure and those diseases but, pursuant to the Agent Orange Act of 1991, has granted presumptive service connection to Vietnam veterans for these diseases. As a practical matter, this means that Vietnam veterans suffering from any of those diseases are presumptively entitled to VA disability compensation, or their families to VA death benefits if the veteran died from these diseases. The number of veterans receiving such compensation has dramatically increased in the last two years as a result of the newly added diseases, so that according to the VA Compensation and

Pension Service, as of February 1, 1995, approximately 2,300 veterans receive VA compensation for Agent Orange related diseases.[11] In addition, the number of latent cases is, of course, unknown—it took almost 40 years for solid tissue cancers to develop in atomic bomb victims in Japan. See *In re "Agent Orange" Prod. Liab. Litig.*, 597 F. Supp. 740, 795 (E.D.N.Y. 1984).

CONCLUSION

Contrary to the government's suggestion, substantial, credible scientific evidence now exists which supports an association between exposure to dioxin and certain cancers and other diseases. The evidence has indeed been sufficient to compel the Secretary of Veterans Affairs to grant presumptive service connection and corresponding VA benefits to Vietnam veterans solely on that basis, pursuant to the Agent Orange Act of 1991.

Respectfully submitted,

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[11] Information provided by facsimile to Gershon M. Ratner by Steven Thornberry, VA Compensation and Pension Service, Feb. 6, 1995.